

SUMMARY

(In accordance with 40 CFR Part 152,
this summary is available for public release after registration.)

STUDY TITLE

Residues of XDE-208 in Non-Grass Animal Feeds from the USA

DATA REQUIREMENTS

USEPA OPPTS 860.1000 Background and 860.1500 Crop Field Trials
OECD Residue Chemistry Studies, Series on Pesticides No. 32

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STUDY COMPLETION DATE

30 April 2013

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STUDY NUMBER

ARA-11-15-01

DAS STUDY ID

110316

REPORT TITLE

Residues of XDE-208 in Non-Grass Animal Feeds from the USA

SUMMARY

The magnitude of residue of XDE-208 and its metabolites X11719474 and X11721061 was determined in alfalfa and clover raw agricultural commodities (RAC). Two applications were made prior to each of three alfalfa cuttings or mature clover harvest interval, with each application targeted at 0.09 lb. ai/acre (~100 g ai/ha). Applications were made at approximately 7-day intervals in spray volumes from 20 to 40 gallons per acre (~200 to 400 L/ha). XDE-208 insecticide was applied as the GF-2372 wettable dispersible granule (WDG) formulation which contains 500 g ai/kg (nominal). Applications were made so that normal commercial harvest would occur 7-days after the last application (7-day pre-harvest interval; PHI). Residue decline was evaluated at one site each for alfalfa and clover with samples collected at 0 and a nominal 7, 14 and 21-days following the last application.

Field trials were conducted at eleven locations for alfalfa and nine locations for clover representing the major commercial growing regions in the USA. Alfalfa trials were conducted in NAFTA Region 1 (one trial in Pennsylvania), Region 5 (Nebraska 3, Kansas 1), Region 7 (Nebraska 1), Region 9 (Colorado 1, Arizona 1), Region 10 (California 1 and Arizona 1), Region 11 (Oregon 1). The alfalfa matrices of forage and hay were collected from three cuttings at nine of the eleven trial locations except for the California trial in which field errors resulted in the loss of the first and third cuttings. Alfalfa silage was collected from four trials and alfalfa seed was collected from three trials.

Clover trials were conducted in NAFTA Region 1 (one trial in New Jersey), Region 2 (Georgia 1), Region 4 (Louisiana 1), Region 5 (Nebraska 1, Kansas 1), Region 6 (Oklahoma 1), Region 7 (Nebraska 1), Region 8 (Texas 1), and Region 10 (California 1). Clover forage and hay were collected from each of the nine trial locations and clover silage was collected from four trial locations.

XDE-208, X11719474, and X11721061 residues were determined using the Dow AgroSciences Crop Method 091031 using Liquid Chromatography and tandem Mass Spectrometry. The limit of quantification (LOQ) and limit of detection (LOD) in each matrix was 0.01 mg/kg and 0.003 mg/kg, respectively, for each analyte. Average concurrent recoveries from alfalfa and clover RAC control samples ranged from 93% to 101% for the parent XDE-208, from 83% to 104% for the metabolite X11719474, and from 93% to 106% for the metabolite X11721061.

In alfalfa forage, the overall average percent recovery \pm standard deviation was 93% \pm 7.1% for XDE-208, 101% \pm 16% for X11719474, and 98% \pm 14% for X11721061. In alfalfa hay, the overall average percent recovery \pm standard deviation was 99% \pm 14% for XDE-208, 104% \pm 7.3% for X11719474, and 106% \pm 7.1% for X11721061. In alfalfa silage, the overall average percent recovery \pm standard deviation was 90% \pm 6.8% for XDE-208, 83% \pm 13% for X11719474, and 103% \pm 6.0% for X11721061. In alfalfa seed, the overall average percent recovery \pm standard deviation was 99% \pm 4.4% for XDE-208, 91% \pm 10% for X11719474, and 100% \pm 9.5% for X11721061.

In clover forage, the overall average percent recovery \pm standard deviation was 95% \pm 14% for XDE-208, 88% \pm 12% for X11719474, and 93% \pm 15% for X11721061. In clover hay, the overall average percent recovery \pm standard deviation was 98% \pm 9.7% for XDE-208, 97% \pm 13% for X11719474, and

103% \pm 11% for X11721061. In clover silage, the overall average percent recovery \pm standard deviation was 101% \pm 8.1% for XDE-208, 95% \pm 12% for X11719474, and 94% \pm 12% for X11721061.

In treated alfalfa forage residues of XDE-208 ranged from 0.562 to 4.18 mg/kg, residues of the metabolite X11719474 ranged from 0.035 to 0.460 mg/kg and residues of the metabolite X11721061 ranged from 0.223 to 2.12 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 4.09 mg/kg for XDE-208, 0.436 mg/kg for X11719474, and 1.86 mg/kg for X11721061. In treated alfalfa hay residues of XDE-208 ranged from 1.45 to 12.5 mg/kg, residues of the metabolite X11719474 ranged from 0.086 to 1.07 mg/kg and residues of the metabolite X11721061 ranged from 0.285 to 4.08 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 11.6 mg/kg for XDE-208, 1.00 mg/kg for X11719474, and 3.55 mg/kg for X11721061. In treated alfalfa silage residues of XDE-208 ranged from 1.56 to 4.37 mg/kg, residues of the metabolite X11719474 ranged from 0.141 to 0.414 mg/kg and residues of the metabolite X11721061 ranged from 0.581 to 1.42 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 4.17 mg/kg for XDE-208, 0.412 mg/kg for X11719474, and 1.38 mg/kg for X11721061. In treated alfalfa seed residues of XDE-208 ranged from 0.203 to 16.3 mg/kg, residues of the metabolite X11719474 ranged from 0.0144 to 0.426 mg/kg and residues of the metabolite X11721061 ranged from 0.072 to 1.86 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 13.1 mg/kg for XDE-208, 0.426 mg/kg for X11719474, and 1.85 mg/kg for X11721061.

In treated clover forage residues of XDE-208 ranged from 0.0927 to 9.26 mg/kg, residues of the metabolite X11719474 ranged from 0.0378 to 1.52 mg/kg and residues of the metabolite X11721061 ranged from 0.241 to 0.873 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 8.71 mg/kg for XDE-208, 1.29 mg/kg for X11719474, and 0.738 mg/kg for X11721061. In treated clover hay residues of XDE-208 ranged from 0.294 to 12.7 mg/kg, residues of the metabolite X11719474 ranged from 0.181 to 1.40 mg/kg and residues of the metabolite X11721061 ranged from 0.226 to 1.96 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 11.4 mg/kg for XDE-208, 1.31 mg/kg for X11719474, and 1.84 mg/kg for X11721061. In treated clover silage residues of XDE-208 ranged from 0.0870 to 3.80 mg/kg, residues of the metabolite X11719474 ranged from 0.049 to 0.127 mg/kg and residues of the metabolite X11721061 ranged from 0.392 to 0.697 mg/kg at 7 \pm 1 day PHI. The highest average field trial residues (HAFT) at a 7 \pm 1 day PHI were 3.33 mg/kg for XDE-208, 0.126 mg/kg for X11719474, and 0.651 mg/kg for X11721061.

Residues in the untreated samples were generally below the limit of detection (ND, <0.003mg/kg) and ranged from ND to 0.0210 mg/kg for XDE-208, ND to 0.0226 mg/kg for X11719474, and ND to 0.0205 mg/kg for the metabolite X11721061.

In general, residues declined with increasing PHI across all tested commodities.

SUMMARY

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STUDY TITLE

Magnitude of the Residues of Sulfoxaflo and its Major Metabolites (X11719474 and X11721061) in or on Pineapple Raw Agricultural and Processed Commodities Following Two Applications with GF-2032 (2012)

TEST GUIDELINES

OPPTS 860.1500 Crop Field Trials, OPPTS 860.1520 Processed Food/Feed,
NAFTA Guidance Document on Data Requirements for Tolerances on
Imported Commodities in the United States and Canada

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STUDY COMPLETION DATE

April 18, 2013

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STUDY NUMBER

120428

REPORT TITLE

Magnitude of the Residues of Sulfoxaflor and its Major Metabolites (X11719474 and X11721061) in or on Pineapple Raw Agricultural and Processed Commodities Following Two Applications with GF-2032 (2012)

SUMMARY

The magnitude and decline of residues of sulfoxaflor and its metabolites (X11719474 and X11721061) was determined in pineapple raw agricultural commodities following two foliar broadcast applications of GF-2032 at the maximum label use rate of 100 g ai/ha/application (0.089 lb ai/A/application) nominally at 21 and 7 days before harvest. The magnitude of sulfoxaflor and its metabolites residues was also determined on pineapple processed commodities following two foliar broadcast applications at a 3× rate. Sulfoxaflor insecticide was applied as the GF-2032 suspension concentrate formulation which contains 240 g ai/L (2 lb ai/gal) (nominal). Applications were made so that normal commercial harvest would occur 1 and 7 days after the last application (1-day and 7-day pre-harvest interval; PHI) ± 1 day. Residue decline was evaluated at four sites with pineapple fruit collected 0, 1, 7, 13-14, 19-21, and 25-28 days PHI. Pineapple fruit for processing was collected at one site and processed into peeled fruit, peel, juice, and process residue (wet bran).

Field trials were conducted during the 2012 growing season at eight locations representing the major pineapple growing regions in the USA and Costa Rica. Three pineapple trials were conducted in NAFTA Zone 13 in Hawaii and five trials in Costa Rica. Residues of sulfoxaflor, and its major metabolites, X11719474 and X11721061, in pineapple RAC and processed commodities were quantitated using Dow AgroSciences LLC analytical methodology found in Study ID 091031 with minor modifications. The limit of quantification (LOQ) and limit of detection (LOD) in all pineapple matrices were 0.01 mg/kg and 0.003 mg/kg, respectively. Combined method verification and concurrent procedural recoveries across all matrices ranged from 73 to 120% for sulfoxaflor, 61 to 116% for X11719474, and 77 to 120% for X11721061.

The results from these trials show that after two foliar applications of GF-2032 at 100 g ai/ha/application (0.089 lb ai/A/application) ±5% nominally at 21 ±1 and 7 ±1 days before harvest, residues of sulfoxaflor ranged from 0.0102 to 0.0836 mg/kg (mean = 0.0355 mg/kg ± 0.0206, n=16) on whole fruit collected 1 DALA and from 0.00735 (<LOQ) to 0.0593 mg/kg (mean = 0.0252 mg/kg ± 0.0148, n=16) on whole fruit collected 7 DALA. Residues of X11719474 and X11721061 were <LOQ in all samples collected 1 and 7 DALA.

Results from the four decline trials show that mean residues of sulfoxaflor do not increase with longer preharvest intervals. At Trial -02, mean sulfoxaflor residues were 0.0480 mg/kg at 0 DALA and 0.0147 mg/kg at 25 DALA. At Trial -03, mean sulfoxaflor residues were 0.0931 mg/kg at 0 DALA and 0.0261 mg/kg at 28 DALA. At Trial -04, mean sulfoxaflor residues were 0.0248 mg/kg at 0 DALA and 0.00783 mg/kg (<LOQ) at 25 DALA. At Trial -05, mean sulfoxaflor residues were 0.0175 mg/kg at 0 DALA and 0.0111 mg/kg at 25 DALA. Residues of X11719474 and X11721061 were <LOQ at all sampling events.

The results from the processing study show that after two 3× rate foliar applications of GF-2032 at 300 g ai/ha/application (0.268 lb ai/A/application) ±5% at 21 and 8 days before normal harvest, mean residues of sulfoxaflor in/on whole fruit, peeled fruit, peel, juice, and process residue (wet bran) were 0.157 mg/kg, 0.0244 mg/kg, 0.350 mg/kg, 0.0138 mg/kg, and 0.0158 mg/kg, respectively, collected 1 DALA. Mean residues of X11719474 in/on whole fruit, peeled fruit, peel, juice, and process residue (wet bran) were <LOQ (0.00645 mg/kg), ND, 0.0120 mg/kg, ND, and ND, respectively. Mean residues of X11721061 in/on whole fruit, peeled fruit, peel, juice, and process residue (wet bran) were ND, ND, <LOQ (0.00739 mg/kg), ND, and ND, respectively. A comparison of the residues in the RAC with those in the processed fractions indicated that residues do not concentrate in peeled fruit, juice, and process residue (wet bran) (processing factor <1). The processing factors for peel are 2.2, 1.9 and 4.9 for sulfoxaflor, X11719474, and X11721061, respectively.